

Decisions taken in the 112th meeting of the Genetic Engineering Appraisal Committee (GEAC) held on 21.09.2011

The 112th meeting of the GEAC was held on 21.9.2011 in the Ministry of Environment & Forests under the chairmanship of Shri M. F. Farooqui, Additional Secretary, MoEF and Chairman, GEAC.

The deliberations and decisions taken in the GEAC meeting in respect of Agenda items 4 to 7 are as follows:

Agenda item No 4 : Consideration of Application for Environmental Release:

4.1 Application for environmental release of two transgenic cotton hybrids namely; WS 103 and WS 106 expressing Cry 1Ac and Cry 1F genes Widestrike = Event 281-24-236) in South Zone by M/S Dow Agro-sciences India Pvt. Ltd , Mumbai.

4.1.1 The Committee considered the application submitted by M/s Dow AgroSciences seeking permission of the GEAC for environmental release of two transgenic Widestrike cotton namely WS103 & WS106 containing *cry1F* (Event 281-24-236) + *cry1Ac* (Event 3006-210-23) on completion of two seasons BRL-I during Kharif 2008 and 2009 and one seasons BRL-II trials during Kharif 2010 in the south zone.

4.1.2 The Committee also noted that BRL-II trials were conducted with two hybrids (WS103 and WS106) at three locations namely Attur, Dharwad and Guntur and seed production in an area of eight acres per hybrid at Attur, Tamil Nadu during kharif 2010 in the south zone under the direct supervision of Director, CICR, Nagpur. The report of BRL-II trials and recommendations of Director, CICR, Nagpur on the safety and efficacy of the product was also noted. .

4.1.3 The Committee also discussed at length the information submitted by the applicant with respect to chronological sequence of development of Widestrike cotton in India details of inserted gene/modification, details of field trials, and summary of the results of various environmental and food feed safety studies submitted to the RCGM/GEAC.

4.1.4 Consolidated comments of the Committee are as given under:

1. Results of acute oral toxicity studies with PAT (phosphinothricin acetyl transferase) protein. Have these been done elsewhere? Please provide references and data.
2. Results of partial PAT ORF containing 77 amino acids from the N-terminal region and 8 additional amino acids from the C-terminal end. This is an additional novel PRF in Widestrike cotton. Acute oral toxicity studies to be done with purified protein encoded by this ORF.
3. Does PAT inactivate any antibiotics that are currently in clinical use/or have been used clinically in the past.
4. Results of the 90 day study on sub-chronic toxicity should be provided to the GEAC. The 'published paper' is to be provided to the Committee; if necessary, the original data tables.
5. In the 90 day study, comparison should be between Widestrike cotton and the corresponding non-transgenic cotton. Why were four conventional bred lines of cotton used?

6. The Widestrike hybrid to be released in India is different from that used in the 90 day sub-chronic toxicity study that was conducted in the USA. The 90 day sub-chronic toxicity study should be conducted again in India with the Widestrike hybrid being released in India and the corresponding non-transgenic hybrid.
7. Poultry feeding study. What are the clinical parameters assessed? Were any differences observed?
8. Feeding study on goats: details about the observed changes in haematology and clinical parameters are to be provided.
9. Environmental biosafety studies. A few differences in rhizospheric microflora are indicated. What are these differences? Pl. elaborate.
10. In the entire document, no data are provided to corroborate the conclusions drawn.
11. Rationale should be provided for expressing PAT genes using different promoters in the two constructs and in the hybrid.
12. No evidence is provided that the stacked genes indeed give better protection than individual genes.
13. If the F1 parents are heterozygous for transgenes, segregation will occur and some of the seeds produced on F1 plants will have only one or the other of the transgenes. Therefore, the seeds produced on F1 plants will be a genetic admixture and their use in sub-chronic toxicity and feeding studies would not give a complete picture of possible adverse effects that individual transgenes might carry. To prevent the above, both male and female parents should have both genes in homozygous condition (this will avoid segregation in the seeds produced on F1 plants). If this is not possible, sub-chronic toxicity and feeding studies should be conducted using seeds from each of the parental lines.
14. Is phosphinothricin/glufosinate registered for use or is it being used as a herbicide in India? Is it being used as a herbicide in any other country?

4.1.5 After detailed deliberations, it was decided that the applicant will make a detailed presentation before the GEAC on the biosafety data generated by the applicant and provide clarification to issues raised by the Committee in the next meeting of the GEAC.

Agenda item No.5: Consideration of applications for confined field trials of transgenic crops (Event selection/ BRL-I) as recommended by the RCGM.

5.1: Permission to conduct event selection trials of transgenic cotton (*Gossypium hirsutum*) namely; LRK-516-DREB-1, LRK-516-DREB-2, LRK-5166-DREB-9 and LRK-5166-DREB-10 containing *DREB 1A* gene by Central Institute for Cotton Research (CICR), Nagpur.

5.1.1 The Committee considered the request of CICR, Nagpur to conduct event selection trials on transgenic cotton (*Gossypium hirsutum*) namely; LRK-516-DREB-1, LRK-516-DREB-2, LRK-5166-DREB-9 and LRK-5166-DREB-10 containing *DREB 1A* gene resistant to drought condition (Abiotic stress) at CICR, Panjari Farm, Nagpur during 2011.

5.1.2 The Committee noted the purpose of the field trials is to test the performance of transgenic events carrying *DREB1A* gene which determines resistance towards abiotic stress (drought) conditions.

5.1.3 It was also noted that the IBSC has recommended the proposal on 02.04.2011; RCGM recommended the proposal in its 102th meeting held on 28.06.2011.

5.1.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials of transgenic cotton (*Gossypium hirsutum*) namely; LRK-516-DREB-1, LRK-516-DREB-2, LRK-5166-DREB-9 and LRK-5166-DREB-10 containing *DREB 1A* gene at CICR, Panjari Farm, Nagpur during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.2 Permission to conduct Biosafety Research Level-1 Trials (BRL-1) on cotton (*Gossypium hirsutum*) events namely UASDBtC-66, UASDBtC-72, UASDBtC-74, UASDBtC-78, UASDBtC-86 (5 independent events of cotton genotypes of RAH-100 carrying *cry1Ac* gene) by University of Agricultural Sciences (UAS), Dharwad .

5.2.1 The Committee considered the request of UAS, Dharwad in the absence of Dr. B.M.Khadi, Principal Scientist, UAS, Dharwad, to conduct Biosafety Research Level-1 Trials (BRL-1) on cotton (*Gossypium hirsutum*) events namely UASDBtC-66, UASDBtC-72, UASDBtC-74, UASDBtC-78, UASDBtC-86 (5 independent events of cotton genotypes of RAH-100 carrying *cry1Ac* gene) at Agricultural Research Stations in UAS, Dharwad and Arabhavi. The above matter was discussed in the absence of Dr BM Khadi (Dean), UAS Dharwad.

5.2.2 The Committee noted the purpose of the field trials is to: evaluate the transgenic cotton events with *cry1Ac* gene for expression of Cry protein in different tissues and the efficacy in controlling target pest and agronomic performance in open field conditions.

5.2.3 It was further noted that the IBSC has recommended the proposal in its 9th meeting held on 23.07.2010, RCGM recommended the proposal in its 102th meeting held on 28.06.2011.[]

5.2.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct Biosafety Research Level-1 Trials (BRL-1) on cotton (*Gossypium hirsutum*) events namely UASDBtC-66, UASDBtC-72, UASDBtC-74, UASDBtC-78, UASDBtC-86 (5 independent events of cotton genotypes of RAH-100 carrying *cry1Ac* gene) at Agricultural Research Stations in UAS, Dharwad and Arabhavi during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.3 Permission to conduct event selection trials on pigeon pea Tur, Red gram (*Cajanus cajan* (L.) Millsp) namely labt_Marutti_L43, labt Asha-L52, labt Asha-L55 (3 transgenic events developed using the same gene construct in the same species; one event in Maruti and two events in Asha genotype) by University of Agricultural Sciences (UAS), Dharwad.

5.3.1 The Committee considered the request of UAS, Dharwad in the absence of Dr. B.M.Khadi, to conduct event selection trials on pigeon pea Tur, Red gram (*Cajanus cajan* (L.) Millsp) namely labt_Marutti_L43, labt Asha-L52, labt Asha-L55 (3 transgenic events developed using the same gene construct in the same species; one event in Maruti and two events in Asha genotype) at Main Agricultural Research Station, UAS, Dharwad. The above matter was discussed in the absence of Dr BM Khadi (Dean), UAS Dharwad.

5.3.2 It was noted by the committee that the IBSC has recommended the proposal in its 9th meeting held on 23.07.2010, RCGM recommended the proposal in its 102th meeting held on 28.06.2011.

5.3.3 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials on pigeon pea Tur, Red gram (*Cajanus cajan* (L.) Millsp) namely labt_Marutti_L43, labt Asha-L52, labt Asha-L55 (3 transgenic events developed using the same gene construct in the same species; one event in Maruti and two events in Asha genotype) at Agricultural Research Station, UAS, Dharwad, during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.4 Permission to conduct Biosafety Research Level-1 Trials (BRL-1) on rice (*Oryza sativa*) events namely MHR03, MHR05, MHR32, MHR174, MHR256, MHR83, MHR90, MHR95, MHR489 and MHR509 containing *cry1Ac* and *cry1Ab* gene by M/s. Metahelix Life Sciences Ltd., Bangalore

5.4.1 The Committee considered the request of M/s. Metahelix Life Sciences Ltd., Bangalore, to conduct Biosafety Research Level-1 Trials (BRL-1) on rice (*Oryza sativa*) events namely MHR03, MHR05, MHR32, MHR174, MHR256, MHR83, MHR90, MHR95, MHR489 and MHR509 containing *cry1Ac* and *cry1Ab* gene in long leased land at Ranga Reddy Districts in Andhra Pradesh. The main purpose of the trial is to validate the agronomical superior and select the most efficacious events(s) against rice stem borer and leaf folder.

5.4.2 The Committee noted the purpose of the field trials is to validate the agronomically superior and the most efficacious events(s) against rice stem borer and leaf folder.

5.4.3 It was also noted that the IBSC has recommended the proposal. RCGM recommended the proposal in its 102th meeting held on 28.06.2011.

5.4.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct Biosafety Research Level-1 trials (BRL-1) on rice (*Oryza sativa*) events namely MHR03, MHR05, MHR32, MHR174, MHR256, MHR83, MHR90, MHR95, MHR489 and MHR509 containing *cry1Ac* and *cry1Ab* gene in long leased land at Ranga Reddy District in Andhra Pradesh during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.5 Permission to conduct Event selection trials with 168 events of transgenic rice and F1 Hybrid seed production (Two cycles per year) from constructs RPD5-RPD17 imported from USA and Belgium, at BASF owned site at Bellathi (Coimbatore) by M/s. BASF India Ltd., New Delhi.

5.5.1 The Committee considered the request of the M/s. BASF India Ltd., New Delhi, to conduct event selection trials with 168 events of transgenic rice and F1 Hybrid seed production (Two cycles per year) from constructs RPD5-RPD17 imported from USA and Belgium, at BASF owned site at Bellathi (Coimbatore).

5.5.2 The Committee noted that the company has also requested for F1 seed production in an area of 6000 m². The objective of seed production is to produce test hybrids between 1-3 female non-GMO cytoplasm male sterile lines and a transgenic event. The produced test

hybrids will be tested in Elite event selection yield trials in different agro-climatic ecosystems in different seasons to select finally the Elite Event .

5.5.3 BASF has extensive experience in producing test hybrids with large number of events (used as males) with 1-3 testers (female lines) in other regions outside India. BASF plans to produce test hybrids locally in India. Hybrids need to be tested in multiple locations and multiple seasons in order to be able to select the elite event. This require such quantities of seed that we believe we will need two cycles of production per year in order to ensure sufficient quantities of good quality seed.

5.5.4 The Committee noted that the purpose of the field trials is to make first selection of events of a given construct after they have been tested in the open field in an Indian environment

5.5.5 It was also noted by the Committee that the IBSC has recommended the proposal on 19.5.2011; RCGM recommended the proposal in its 102th meeting held on 28.06.2011.

5.5.6 After detailed deliberation, it was decided to obtain information on (i) No. of events for each gene (ii) Origin and source of gene and (iii) purpose and objective of the proposed transformation. Decision on the proposal was therefore deferred. It was also decided that the applicant will make a detailed presentation before the GEAC in the next meeting.

5.6 Permission to conduct event selection trial of salt tolerant rice (*Oryza sativa* L.) events containing the *nhx1* gene by M/s. Maharashtra Hybrid Seeds Company Ltd. (MAHYCO), Mumbai.

5.6.1 The Committee considered the request of MAHYCO, Mumbai to conduct event selection trials with of salt tolerant rice (*Oryza sativa* L.) events containing the *nhx1* gene at company owned farms (Anand Nagar, Nizamabad) Andhra Pradesh.

5.6.2. The Committee noted the purpose of the field trials is:to evaluate the efficacy of transgenic rice events expressing the OsNHX1 protein compared to their non-transgenic counterparts and checks for salinity tolerance.

5.6.3 It was also noted that the IBSC has recommended the proposal in its 9th meeting held on 15.6.2011, RCGM recommended the proposal in its 102th meeting held on 28.06.2011.

5.6.4 The Committee noted that the transgenic rice expressing ***nhx1* gene** have *gusA* gene in their expression cassettes. Members opined that biosafety issues that are to be addressed in respect of such transgenic crops are more complex as the transcriptional factors are known to trigger production of a large number of proteins downstream. These issues need to be further discussed and guidelines for biosafety testing need to be developed. The Committee was also of the view that because of the presence of gratuitous gene such as *gus* in the food crops, it may not be considered for environmental release when such a proposal is mooted by the project proponents.

5.6.5 After detailed deliberations, the Committee did not approve the request for event selection for eventual commercial development because both constructs contain *gus* gene. However, these are approved for contained research only.

5.7 Permission to conduct second year BRL-II trials of Bollgard II R Roundup Ready Flex (BGII RRFTM cotton hybrids MRC 8347 BGII RRF TM and MRC 8351 BGII RRF TM

in Central and South Zones containing cry 1Ac, cry 2Ab genes and cp4epsps gene (Event MON 15985 X MON 88913) by M/s. Mahyco.

5.7.1 The Committee noted that the GEAC in its meeting held on 6.7.2011 decided to reject the appeal submitted by M/s. Mahyco to consider the BRL-I data generated during Kharif 2010, meeting held on 6.7.2011. The applicant has now submitted an application seeking permission of the GEAC to conduct BRL-II trials of Bollgard II Roundup Ready Flex (BGII RRFTM) cotton hybrids during Kharif 2011.

5.7.2 The Committee noted that the trials will be conducted with cotton hybrids namely MRC 8347 BGII RRFTM and MRC 8351 BGII RRFTM containing (Event MON 15985 X MON 88913) in Central and South Zones. The proposed locations include Central Institute for Cotton Research (CICR) farm, Nagpur, Main Cottage Research Station, Surat (NAU, Navsari), Agriculture College Farm, Khandwa, long leased farm Village-Karalpudi, Distt Guntur, Agriculture Research Station, Distt, Belgaum (UAS, Dharwad), Central Institute for Cotton Research (CICR Farm), Coimbatore.

5.7.3 The Committee also noted the main objective of the trials is to:

- (I) study the weed control efficacy in BGII RRFTM hybrids with Glyphosate tolerant trait (MON 88913) with post –emergent application of Roundup (MON 76366) on RRFTM cotton hybrids.
- (II) estimate level of expression of cry 1Ac, cry 2Ab genes and CP4 EPSPS proteins in various plant parts at different crop growth stages.
- (iii) Estimate protein expression data of cry 1Ac, cry 2Ab genes and CP4 EPSPS in BG II RRFTM cotton hybrids will be recorded at the time of the each BG II application at 60, 80, 100, 120, 140 and 160 days after sowing at all trial locations. In addition to the protein expression data for CP4 EPSPS will be recorded at the time of the Roundup application.
- (iv) study the efficacy and comparison of the level of infestation of the target insect pests on BGII RRFTM hybrids, BGII counterparts and checks.
- (v) observe with respect to growth habit, life cycle, plant height, impact on pollinator species and indicators of changes in weediness potential of BG IIRRFTM hybrids, non-transgenic counterparts and checks.
- (vi) monitoring the occurrence of beneficial and non–target insects on BGII RRFTM hybrids, BGII counterparts and checks.
- (vii) assess effect of cry 1Ac, cry 2Ab genes and CP4 EPSPS protein on soil microflora, earthworms and soil insect (Collembola) related to rhizosphere on the soil of BG II RRFTM, BGII hybrids and checks. Data should be recorded during pre and post spray of Roundup formulation (MON 76366) and pre planting and post harvesting stage.
- (viii) assess carry- over effects (within 30 days of post harvest) of protein residues, if any, of BGII RRFTM cotton hybrids with reference to the presence / absence of cry 1Ac, Cry 2Ab and CP4 EPSPS proteins in different soil depths (maximum up to one meter) at one location.
- (ix) estimate cost of chemical weed control (Round up application) vis-visa manual and mechanical weed control. Estimation of benefit: cost ratio of the BGII RRFtm technology.

5.7.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct second year BRL-II trials of

Bollgard II R Roundup Ready Flex (BGII RRFTM) cotton hybrids namely MRC 8347 BGII RRF™ and MRC 8351 BGII RRF™ containing cry 1Ac, cry 2Ab genes and cp4epsps gene (Event MON 15985 X MON 88913 in the Central and South Zones during the appropriate season in **2011-12** subject to the conditions that (i) Protocol for BRL-2 trials shall not include RRF refugia and (ii) submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.8 Permission to conduct event selection trials of fourteen transgenic rice (*Oryza sativa L.*) events generated using Bt39 (Cry1C+Cry2Ad), Bt40 (Cry1Ab+Cry2Ad) construct and Bt43 (Cry1C+Cry1Ab) constructs by M/s. E.I. DuPont India Pvt. Ltd., Hyderabad.

5.8.1 The Committee considered the request of M/s. E.I. DuPont India Pvt. Ltd., DuPont Knowledge Center, Hyderabad to conduct event selection trials of following transgenic rice (*Oryza sativa L.*) events developed from three different constructs i.e. Bt39 (Cry1C+Cry2Ad), Bt40 (Cry1Ab+Cry2Ad) construct and Bt43 (Cry1C+Cry1Ab):

- Six events generated using Bt39 (Cry1C+Cry2Ad) construct, namely Bt39-101, Bt39-102, Bt39-103, Bt39-104, Bt39-105 and Bt39-106 of T3 generation.
- Four events generated using Bt40 (Cry1Ab+Cry2Ad) construct, namely Bt40-101, Bt40-102, Bt40-103 and Bt40-104 of T3 generation.
- Six events generated using Bt43 (Cry1C+Cry1Ab) construct, namely Bt43-101, Bt43-102, Bt43-103, Bt43-104, Bt43-105 and Bt43-106 of T3 generation.

All the events have been developed by transforming elite indica rice, IRV95 and are single copy and selectable marker free.

5.8.2 The Committee noted that the objective of the trial is to evaluate the efficacy of dual molecular stacked *cry* genes in Bt rice events against Yellow stem borer and Rice leaf folder pests in the confined field trial.

5.8.3 The Committee also noted that the trials will be conducted at Yeldurti Mandal, Masaipet Village, Medak District, Andhra Pradesh in an area of 1 acre (during Dec., 2011).

5.8.4 It was further noted that the IBSC in its 14th meeting has recommended the proposal on 10.06.2011. RCGM also recommended the proposal in its 103rd meeting held on 26.07.2011.

5.8.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials of fourteen transgenic rice (*Oryza sativa L.*) events generated using Bt39 (Cry1C+Cry2Ad), Bt40 (Cry1Ab+Cry2Ad) construct and Bt43 (Cry1C+Cry1Ab) constructs at Medak District, Andhra Pradesh during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted..

5.9 Permission to conduct event selection trials of 20 events of transgenic rice (*Oryza sativa L.*) generated using SPT1 construct expressing OS-MSCA1, ZM-AA1 and DsRed2 protein M/s. E.I. DuPont India Pvt. Ltd., Hyderabad.

5.9.1 The Committee considered the request of M/s. E.I. DuPont India Pvt. Ltd., DuPont Knowledge Center, Hyderabad to conduct event selection trials on transgenic rice (*Oryza sativa L.*) events generated using SPT1 construct, namely SPT1-3001, SPT1-3002, SPT1-3003, SPT1-3004, SPT1-3005, SPT1-3006, SPT1-3007, SPT1-3008, SPT1-3009, SPT1-

3010, SPT1-3011, SPT1-3012, SPT1-3013, SPT1-3014, SPT1-3015, SPT1-3016, SPT1-3017, SPT1-3018, SPT1-3019 and SPT1-3020 of BC2 generation expressing OS-MSCA1, ZM-AA1 and DsRed2 protein at Medak District, Andhra Pradesh.

5.9.2 The Committee noted the purpose of the study is (i) to assess the frequency of transgene transmission through pollen in different events; (ii) to assess the seed productivity of the events. And (iii) to evaluate the expression levels of DsRed2 and ZM-AA1 in tissues of Rice SPT maintainer events.

5.9.3 It was further noted that the IBSC in its 14th meeting has recommended the proposal on 10.06.201. RCGM also recommended the proposal in its 103rd meeting held on 26.07.2011.

5.9.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials event selection trials of 20 events of transgenic rice (*Oryza sativa L.*) generated using SPT1 construct expressing OS-MSCA1, ZM-AA1 and DsRed2 protein at Medak District, Andhra Pradesh during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.10 Permission to conduct event selection trials of 20 events of transgenic rice (*Oryza sativa L.*) generated using SPT6 construct, expressing OS-MSCA1, ZM-AA1 and DsRed2 protein by M/s. E.I. Dupont India Pvt. Ltd., Hyderabad.

5.10.1 The Committee considered the request of M/s. E.I. Dupont India Pvt. Ltd., Dupont Knowledge Center, Hyderabad to conduct event selection trials on transgenic rice (*Oryza sativa L.*) events generated using SPT6 construct, namely SPT6-1001, SPT6-1002, SPT6-1003, SPT6-1004, S SPT6-1005, SPT6-1006, SPT6-1007, SPT6-1008, SPT6-1009, SPT6-1010, SPT6-1011, SPT6-1012, SPT6-1013, SPT6-1014, SPT6-1015, SPT6-1016, SPT6-1017, SPT6-1018, SPT6-1019 and SPT6-1020 expressing OS-MSCA1, ZM-AA1 and DsRed2 protein at Medak District, Andhra Pradesh

5.10.2 The Committee noted that the purpose of the study is: (i) to assess the frequency of transgene transmission through pollen in different events (ii) to assess the seed productivity of the events and (iii) to evaluate the expression levels of DsRed2 and ZM-AA1 in tissues of Rice SPT maintainer events.

5.10.3 It was also noted that the IBSC in its 14th meeting has recommended the proposal on 10.06.201. RCGM also recommended the proposal in its 103rd meeting held on 26.07.2011.

5.10.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials of 20 events of transgenic rice (*Oryza sativa L.*) generated using SPT6 construct, expressing OS-MSCA1, ZM-AA1 and DsRed2 protein at Medak District, Andhra Pradesh during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.11 Permission to conduct event selection trials of 20 events of transgenic Pigeonpea carrying synthetic *cry1Ac* gene by International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Patancheru.

5.11.1 The Committee considered the request of International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Patancheru to conduct event selection trials on Pigeonpea

[*Cajanus cajan* (L.) Millisp.] events namely R3-2, R3-4, R3-18, R4-2-6, R4-2-26, R4-5-13, R4-5-14, R39-4-9 and R39-4-25 (T2 generation of R-events developed with pRD400 carrying synthetic *cry1Ac* gene); Z9-4-7, Z9-4-13, Z9-4-14, Z9-4-16, Z9-4-17, Z9-4-22, Z9-4-30 (T3 generation of Z-events developed with pZP200 carrying synthetic *cry1Ac* gene); C10-3-20-14, C10-3-20-24, C13-1-9-2, C13-1-9-8, C13-1-15-4, C13-1-15-8, C15-4-21-3, C15-4-21-10, C20-1-7-6 and C20-1-7-9 (T3 generation of C-events developed with pCAMBIA2310 carrying synthetic *cry1Ac* gene); Control (ICPL 87), Control (ICPL 332) at ICRISAT, experimental field in Patancheru.

5.11.2 The Committee also noted the purpose of the study is:

- i) The phenotyping of four events of transgenic pigeon (Var. ICPL 88039 carrying the synthetic *cry1Ac* gene driven by the 35S CaMV promoter and its intended to be carried out for event selection.
- ii) The transgenic events will be planted in replicated along with the untransformed control, susceptible and the resistant check ICPL 88039, ICPL 87 and ICPL 332. First instar and the third instar larvae of *Helicoverpa armigera* will be inoculated in the vegetative and the pod stages of the crop to study the response of the larvae to the transgenic events.
- iii) Larval feed score, larval survival, larval weight will be scored comparing to the control plants and will be analysed to select the best performing event. The plants will be analyzed by ELISA at different stages of growth and development.

5.11.3 It was also noted that the IBSC in its meeting held on 16.06.2011 has recommended the proposal. RCGM also recommended the proposal in its 103rd meeting held on 26.07.2011.

5.11.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials event selection trials of 20 events of transgenic Pigeon pea carrying synthetic *cry1Ac* gene at Patancheru during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.12 Permission to conduct event selection trials of 9 events of transgenic Groundnut (*Arachis hypogaea* L.) containing tobacco streak virus coat protein gene by International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Patancheru.

5.12.1 The Committee considered the request of International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Patancheru to conduct event selection trials on Groundnut (*Arachis hypogaea* L.) events namely GN TSV1, GN TSV3, GN TSV9, GN TSV30, GN TSV31, GN TSV48, GN TSV94, GN TSV101 and Control (JL 24) containing Tobacco Streak Virus (TSV) coat protein gene. The trials will be conducted at ICRISAT, experimental field, Patancheru..

5.12.2 The Committee noted that the purpose of the study is:

- i) Test plants will be grown among the TSV infected parthenium plants to encourage infective pollen test plants followed by the release of thrips to augment the natural infection of TSV under field condition.
- ii) Molecular analysis of the transgenic and non-transgenic plants within and outside the test plots will be carried out by PCR, RT-PCR, Southern hybridization, ELISA and western blotting to monitor the transgenic nature of the test plants and ascertain the gene flow, if any, within and between the plots.

iii) The untransformed controls grown within the plots as a refuge will be analyzed for presence of transgenes to study the gene flow if any. Periodic observations on the performance of transgenic plants will be recorded using the following parameters:

- Number of plants infected and also delayed symptom expression
- Symptomatology
- Disease severity levels
- Total number of pods plant
- Pod and haulm yield

5.12.3 It was further noted that the IBSC in its meeting held on 16.06.2011 has recommended the proposal. RCGM also recommended the proposal in its 103rd meeting held on 26.07.2011.

5.12.4 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials of 9 events of transgenic Groundnut (*Arachis hypogaea L.*) containing tobacco streak virus coat protein gene during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted..

5.13 Permission to conduct event selection trials of 8 events of Groundnut (*Arachis hypogaea L.*) containing DREB 1 gene by International Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Patancheru.

5.13.1 The Committee considered the request of Crops Research Institute for the Semi-Arid Tropics (ICRISAT), Patancheru has requested permission to conduct event selection trials on Groundnut (*Arachis hypogaea L.*) events namely GNRD2, GNRD11, GNRD12, GNRD19, GNRD20, GNRD33, Control (JL24) and Control (ICGV86031) containing DREB 1 gene at ICRISAT, experimental field, Patancheru.

5.13.2 The Committee noted the purpose of the study is:

- i) The phenotyping of six events of transgenic groundnut (var. JL24) carrying the *DREB1A* gene derived from *Arabidopsis thaliana* by the drought-responsive promoter of rd29A gene from *A. thaliana*
- ii) Yield response among the transgenic events in comparison to control genotypes under imposed intermittent drought stress would be evaluated by directly planting in soil.
- iii) These events have previously shown promising results in greenhouse and contained trials conducted in lysimeters and will now be evaluated for yield response by sowing in confined fields directly.

5.13.3 It was also noted that the IBSC in its meeting held on 16.06.2011 has recommended the proposal. RCGM also recommended the proposal in its 103rd meeting held on 26.07.2011.

5.13.4 The Committee noted that the transgenic groundnut to improve its stress tolerance; expresses DREB transcription factors namely DREB1A. Members opined that biosafety issues that are to be addressed in respect of such transgenic crops are more complex as the transcriptional factors are known to trigger production of a large number of proteins downstream. These issues need to be further discussed and guidelines for biosafety testing need to be developed.

5.13.5 After detailed deliberations, the Committee approved the request for event selection. trials of 8 events of Groundnut (*Arachis hypogaea* L.) containing DREB 1 gene at Patancheru during the appropriate season 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted. However, the applicant was cautioned about the complexities associated with transcription factors as these are known to trigger production of a large number of proteins downstream which in turn raise issues in dealing with toxicology studies, etc; required for regulatory approval.

5.14 Permission to conduct Biosafety Research Level-1 (BRL-1) trials second year on transgenic mustard (*Brassica juncea*) containing *bar*, *barnase* and *barstar* genes [Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) & bn 3.6xmodbs 2.99 (Hybrid DMH-11) under the coordination of Directorate of Rapeseed-Mustard Research, Bharatpur at six locations by Centre for Genetic Manipulation of Crop Plants (CGMCP), University of Delhi South Campus, New Delhi.

5.14.1 The Committee considered the request of 'The Centre for Genetic Manipulation of Crop Plants (CGMCP)', University of Delhi, South Campus to conduct Biosafety Research Level-I (BRL-I) trials second year on transgenic mustard (*Brassica juncea*) containing *bar*, *barnase* and *barstar* genes [Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) & bn 3.6xmodbs 2.99 (Hybrid DMH-11), trials will be conducted under the coordination of Directorate of Rapeseed-Mustard Research, Bharatpur at six locations i.e. Bharatpur, Alwar, Sriganganagar, Kanpur, Ludhiana and Morena.

5.14.2 The Committee noted that the Event bn 3.6 (Barnase line) and event modbs 2.99 (Barstar line) was selected in RLM 198 and Varuna variety of *B. juncea* respectively. These events in two varieties were introduced into many good combiners for development of hybrids through backcrossing. Event bn 3.6 and modbs 2.99 were backcrossed into variety Varuna and east-European type mustard line EH-2 respectively which were further crossed to form F1 hybrid DMH-11.

5.14.3 The Committee noted that the purpose of the study is:

- i) To collect the data on reproductive and survival biology of plant.
- ii) Comparative Assessment of Potential for Weediness and Aggressiveness: Biomass estimation of the plant samples collected from all the BRL- I trial sites at the time intervals of 30, 60 days after sowing and at maturity (at the time of harvest).
- iii) Pollination behaviour for self compatibility and pollen viability.
- iv) Non target adverse effects
 - Impact on beneficial organisms: This would include observations honey bees and any other biological control organisms.
 - Impact on soil microflora: Impact on soil microflora mainly bacterial and fungal populations needs to be studied at regular intervals viz. 30, 60, 90, 120 and 150 days. The study would be conducted by Institute of Microbial technology (IMTech), Chandigarh.
- v) Compositional Analyses of Key Component: The seeds and leaves and oil from the seeds would be extracted from the transgenic mustard hybrid DMH-11, the transgenic parents and the control and the different key components would be estimated.
- vi) Collection of Material for Feeding Studies: Transgenic mustard seeds (for feeding studies on broiler chicken) and transgenic mustard leaves and stems (for feeding study on rabbits and goats) from the transgenic mustard hybrid DMH-11, the transgenic parents and the control would be collected from BRL-I trials and

transported to the Contract Research Organization assigned for the conduct of the study.

5.14.4 It was also noted that the trials will be done in Randomized Complete Block Design with six replications with transgenic and non-transgenic mustard hybrids.

5.14.5 It was also noted that the IBSC in its meeting held on 24.06.2011 has recommended the proposal. RCGM also recommended the proposal in its 103rd meeting held on 26.07.2011.

5.14.6 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct second year Biosafety Research Level-1 (BRL-1) trials on transgenic mustard (*Brassica juncea*) containing *bar*, *barnase* and *barstar* genes [Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) & bn 3.6xmodbs 2.99 (Hybrid DMH-11) under the coordination of Directorate of Rapeseed-Mustard Research, Bharatpur during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.15 Permission to conduct environmental safety studies on transgenic mustard (*Brassica juncea*) containing *bar*, *barnase* and *barstar* genes [Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) & bn 3.6xmodbs 2.99 (Hybrid DMH-11) under the coordination of Directorate of Rapeseed-Mustard Research, Bharatpur at one location (Bawana, Delhi) by the 'Centre for Genetic Manipulation of Crop Plants (CGMCP)', University of Delhi South Campus, New Delhi.

5.15.1 The Committee considered the request of the 'Centre for Genetic Manipulation of Crop Plants (CGMCP)', University of Delhi South Campus, to conduct environmental safety studies on transgenic mustard (*Brassica juncea*) containing *bar*, *barnase* and *barstar* genes [Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) & bn 3.6xmodbs 2.99 (Hybrid DMH-11).

5.15.2 The Committee noted that the trial will be conducted under the coordination of Directorate of Rapeseed-Mustard Research, Bharatpur at one location (Bawana, Delhi).

5.15.3 The Committee also noted that the purpose of the proposed study is to:

- i) The pollen morphology and physiology
- ii) Biomass production studies will be conducted where sample will be taken at different intervals such 30 days after sowing, 60 days after sowing and at maturity.
- iii) Weediness potential and aggressiveness paramaters such as seed germination and vigour test and speed of germination
- iv) The expression analysis of *bar*, *barnase* and *barstar* genes in different tissues of transgenic *B. juncea*.

5.15.4 It was further noted that the IBSC in its meeting held on 24.06.2011 has recommended the proposal. RCGM also recommended the proposal in its 103rd meeting held on 26.07.2011.

5.15.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct environmental safety studies on transgenic mustard (*Brassica juncea*) containing *bar*, *barnase* and *barstar* genes [Events bn 3.6 (Barnase Line), modbs 2.99 (Barstar Line) & bn 3.6xmodbs 2.99 (Hybrid DMH-11) under the coordination of Directorate of Rapeseed-Mustard Research, Bharatpur at one

location (Bawana, Delhi) during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.16 Permission to conduct experimental seed production of high oleic *Brassica juncea* line (event HO3.18) selected in 'O' erucic line VH-486 using antisense to *fad2* gene from *Brassica rapa* by the 'Centre for Genetic Manipulation of Crop Plants (CGMCP)' University of Delhi South Campus, New Delhi

5.16.1 The Committee considered the request of 'Centre for Genetic Manipulation of Crop Plants (CGMCP)', University of Delhi, South Campus to conduct experimental seed production of high oleic *Brassica juncea* line (event HO3.18) selected in 'O' erucic line VH-486 using antisense to *fad2* gene from *Brassica rapa*.

5.16.2 The Committee noted that this line has altered oil composition vis a vis all the other mustard varieties. The oleic acid is 75% and 10% each of linoleic and linolenic acids are present. They want to test the nutritional superiority of this oil.

5.16.3 The Committee also noted that the seed production will be conducted at Delhi University's own land in an area of 200 sq m.

5.16.4 It was also noted that the IBSC in its meeting held on 24.06.2011 has recommended the proposal. RCGM also recommended the proposal in its 103rd meeting held on 26.07.2011.

5.16.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct experimental seed production of high oleic *Brassica juncea* line (event HO3.18) selected in 'O' erucic line VH-486 using antisense to *fad2* gene from *Brassica rapa* during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the seed production would be conducted.

5.17 Permission to conduct second year BRL-I trials to analyze the effect of *Azotobacter* mutant strains on wheat in terms of yield, protein content, biomass etc; by National Research Centre on Plant Biotechnology (NRCPB), Indian Agricultural Research Institute (IARI), New Delhi.

5.17.1 The Committee noted that the GEAC in its meeting held on 12.5.2010 had approved the request for conduct of BRL-I trials to analyze the effect of *Azotobacter* mutant strains on wheat in terms of yield, protein content, biomass etc. by growing wheat inoculated with *Azotobacter* strains (both wild and mutants) generated by *in vitro* manipulations) in confined conditions by NRCPB.

5.17.2 The Committee further noted that the present request of NRCPB is for conduct of second year BRL-I trials in confined conditions by NRCPB at IARI farm, New Delhi. It was also noted that the IBSC has recommended the proposal in its 16th meeting held on 28.7.2011, RCGM recommended the proposal in its 104th meeting held on 30.8.2011.

5.17.3 In view of the above stated facts and taking into consideration the recommendations of the RCGM, Committee approved the request to conduct second year BRL-I trials to analyze the effect of *Azotobacter* mutant strains on wheat in terms of yield, protein content,

biomass etc during the appropriate season in **2011-12** subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.18 Permission to conduct event selection trials of ten transgenic potato events containing *GA20 Oxidase 1* gene by Central Potato Research Institute, Shimla.

5.18.1 The Committee considered the request of CPRI, Shimla to conduct event selection trials on ten transgenic potato events namely; KS 1, KS 2, KS 3, KS 5, KS 6, KS 8, KS 11, KH 11, KH 79 and KH 90 containing *GA20 Oxidase 1 gene*. The trials will be conducted at CPRI research station at Jalandhar.

5.18.2 The Committee noted the purpose of the trials:

1. Strip trial with dwarf potato clones for evaluation of plant height, harvest index and tuber yield;
2. The experiment will be conducted by planting each clone in single lines. Non transgenic plants of Kufri Surya and Kufri Himalini will serve as control
3. Data will be collected on plant height, number of nodes, total biomass at the time of harvest and tuber yield.
4. Harvest index of transgenic plants will be compared with control plants to find out any advantage in transgenic plants. .

5.18.3 It was also noted by the Committee that the IBSC has recommended the proposal; RCGM recommended the proposal in its 104th meeting held on 30.8.2011.

5.18.4 Member Secretary informed that the GEAC in its earlier meeting had permitted CPRI to conduct event selection trials containing *GA20 Oxidase 1* gene on 10 transgenic dwarf potato in its 93rd meeting held on 13.5.2009.

5.18.5 In view of the above stated facts and taking into consideration the recommendations of the RCGM, the Committee approved the request to conduct event selection trials of ten transgenic potato events containing *GA20 Oxidase 1* gene at CPRI, RS, Jalandhar during the appropriate season in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

5.19 Permission to conduct seed production of WideStrike cotton hybrids namely; WS 103 and WS 106 expressing WideStrike trait (Cry 1F event 281-24-236 + Cry1Ac event 3006-210-23) in South zone by M/s. Dow AgroSciences India Pvt. Ltd., Mumbai.

5.19.1 The Committee noted that the request of M/s. Dow AgroSciences India Pvt. Ltd., Mumbai to conduct seed production of WideStrike hybrids WS103 and, WS-106 in an area of 60 acres (30 acres/ hybrid) at one location in Attur, (Tamil Nadu) or Andhra Pradesh during Kharif 2011 was considered by the GEAC in its 111st meeting held on 6.7.2011 wherein the applicant was advised to submit clarifications on (i) What basis the request has been made and (ii) the total seed production done so far and its utilization.

5.19.2 The Committee considered the point wise clarifications submitted by the applicant:

- (i) The GEAC in its meeting held on 30.7.2010 had approved seed production with WideStrike cotton hybrids namely; WS 103 and WS 106 in South zone during Kharif 2010 in 8 acres during Kharif -2010. Since the BRL-II trials are in the final stages of completion more seeds may be required for conducting necessary regulatory trials, internal trials and SAU trials as required in future.

(ii) The seed quantities available in stock are 11.15 and 57.5.kg of WS 103 and WS 104 respectively as per details given below:

S.N.	Locations	Hybrids	Net Area planted (Acres)	Quantity (ginned seed cotton)
1.	Hyderabad, AP (Rabi-2008)	WS -103	0.26	2.15 Kg*
2.	Hyderabad, AP (Kharif -2009)	WS -106	0.19	25.5 Kg
3.	Attur, T.N. (kharif - 2010)	WS -103 & WS -106	1 4	9 Kg 32 Kg
Current total available quantity WS-103				11.15 Kg
WS-106				57.5 Kg

*Quantity of hybrid seeds produced was very low due to off season conditions.

5.19.3 The Company has also informed that the current stock of seeds may not be sufficient for future trials in the South and Central Zones. The Committee considered the following requirement for seeds as indicated by the applicant for further trials /tests:

Central zone: BRL-II trials in 8 locations in 2011 or later (7.5.kg each zone).

South zone: 10 SAUs trials in 2011-2012 after environmental release (10 kg approx).

100 field demonstrations of WS-103 and WS-106 in farmer's fields in 2011 and 2012 in south zone after environmental release. (Approx 100 kg seed each hybrid).

5.19.4 The Committee noted that the applicant's request for seed production for environmental release does not merit consideration at this stage. The Committee opined that the applicant may submit a revised estimate based on the seed requirement for BRL-II trials in other zones and additional food/feed safety studies based on the query raised by the GEAC in agenda item 4.1. It was also decided to consider this issue along with agenda item no 4.1 in the next GEAC meeting. Decision on the proposal therefore, was deferred.

5.20 Request for extension of validity to conduct BRL-II trials and seed production of transgenic corn hybrids (Events MON 89034 X NK 603) from Rabi 2010- 2011 and Kharif 2011 to Rabi 2011-12 and Kharif 2012 by M/s. Monsanto India Ltd.

5.20.1 The Committee noted that the GEAC in its meeting held on 8.12.2010 had accorded approval for conduct of BRL-II trials of transgenic corn hybrids, namely Hishell and 900MGold (Events MON 89034 and NK603) containing *cry 1A.105*, *cry2Ab2* and *CP4epsps* genes during Rabi in 5 locations and Kharif -2011 in 9 locations. However, the trials could be completed only at one location in UAS Dharwad during Rabi 2010-11

5.20.2 The present request is for conducting BRL II trials during Rabi -2011-2012 and Kharif -2012 at locations indicated below:

S.No	Rabi -2011-2012	Kharif -2012
1	Andhra Pradesh	Gujarat
2	Karnataka	Haryana ,
3	Bihar	Punjab
4	Maharashtra	Maharashtra
5	Gujarat	Tamilnadu
6	Tamilnadu	Karnataka ,

7		Andhra Pradesh
8		Rajasthan
9		Uttar Pradesh

5.20.3 The Committee observed that the applicant has also requested to allow seed production in an area of 25 acres during the revised period as they could not undertake the same earlier.

5.20.4 In view of the above clarifications submitted by the applicant, the GEAC approved the request for extension of validity to conduct BRL-II trials and seed production of transgenic corn hybrids (Events MON 89034 X NK 603) during the appropriate seasons in 2011-12 subject to submission of NOC from the respective State Department of Agriculture where the trials would be conducted.

Agenda Item No 6: Consideration of applications related to Pharmaceuticals

6.1 Permission to import Tetravalent Dengue Vaccine for Phase II Clinical trials from Sanofi Pasteur, SA Lyon, France to study Immunogenicity and Safety in India by M/s Sanofi Pasteur India Pvt. Ltd, Mumbai (Protocol No CYD 47).

6.1.1 The Committee noted that M/s Sanofi Pasteur India Pvt. Ltd, Mumbai, has sought permission to import Tetravalent Dengue Vaccine from France for Phase II Clinical trials from Sanofi Pasteur, SA Lyon, France to study test Immunogenicity and Safety in India in healthy subjects Aged 18 to 45 Years in India. Internal name of the vaccine is: CYD Dengue Vaccine—International name (WHO): Tetravalent Dengue Vaccine (Live, attenuated).

6.1.2 It was also noted that the DCGI has accorded approval for import Tetravalent Dengue Vaccine for Phase II Clinical trials from Sanofi Pasteur, SA Lyon, France to study Immunogenicity and Safety in India. However, it was decided to await comments from experts before considering the proposal. Decision on the proposal was therefore deferred.

Agenda Item No 7: Other items

7.1 Permission to import transgenic Soybean Oil by three companies viz. M/s. Bayer BioSciences Pvt. Ltd, Gurgaon, M/s by BASF India Ltd and M/s Monsanto Holdings Pvt. Ltd.

7.1.1 The GEAC in its earlier meetings held on 8.7.2009, 5.11.2010 and 9.2.2011 had considered the three requests for import of Soybean oil from the following applicants:

- i. Permission to import transgenic Liberty Link Soybean Oil from USA by M/s. Bayer BioSciences Pvt. Ltd, Gurgaon.
- ii. Import of crude degummed oil derived from BPS-CV127-9 soybean (CV127) from Brazil by BASF India Ltd.
- iii. Import of crude degummed oil produced from GenuityTM Insect Protected Roundup Ready 2 yield^R (BtRR2Y) soybean (breeding stack of Events MON87701XMON89788) from Brazil by M/s Monsanto Holdings Pvt. Ltd.

7.1.2 The Committee considered the following clarifications received from M/s Bayer Biosciences and M/s Monsanto Holdings Pvt Ltd:

- i. All the safety approvals have been taken for Glufosinate Tolerant trait.
- ii. A study was conducted to validate an ELISA method (QualiPlateKit for PAT, cat#AP014NWV10, EnviroLogix) for the determination of phosphinothricin acetyltransferase (PAT) in soybean oil under Good Laboratory Practice Standards (GLPs). In all of the tested LL Soybean (gene event A2704-12 and A 5547-127) oil samples, PAT protein can't be detected (was below detectable level) (Carringer and Langevin 2010 M-395304-01-1 and Carringer and Langevin 2010 M-395296-01-1. In the case of detection of the PAT protein the lowest limit of quantification is 0.063 ng/mL oil (Carringer and Langevin 2010 M-395304-01-1).
- iii. 23 countries are importing GM Soybean oil. The Liberty Link Soybean has been approved for cultivation in 1996 and for food/feed in 1998.
- iv. Worldwide, approximately 35 countries have developed some form of labeling requirement (both mandatory and voluntary) for GM foods, including European Union (EU), China, Australia, New Zealand, Japan, South Korea and Taiwan.
- v. Imported crude degummed soy oil is further subjected to processing to obtain refined, bleached, deodorized (RBD) oil- which is used for human consumption. The by- products namely acid oil and soya fatty acid distillate are used in paint and soap industry respectively.
- vi. Samples of crude degummed and refined oil from BtRR2Y soybeans (Events MON 87701 and MON 89788) were subjected to PCR based DNA detection and immunodiagnostic kit based protein detection methods. Laboratory reports confirm that there is no detectable DNA or protein in the final product of oil derived from BtRR2Y soybean.
- vii. The composition of crude oil/degummed oil/refined oil are representative of the source seed, but vary with the level of purification process involved. Crude oil would be the most representative of seed composition, degummed oil will be missing any phospholipids/gums/waxes, and the refined oil is further purified to remove any color, residual free fatty acids, metals, and oxidation products. Refined soybean oil is 100% fat, therefore, the composition includes individual fatty acids and vitamin E only.

7.1.3 The Committee also deliberated on issues relating to (i) requirement of labelling soybean oil in other countries; (ii) position on the matter under various laws existing in the country; (iii) role and mandate of GEAC.

7.1.4 The Committee further noted that the GEAC in its earlier meetings has approved the following:

- (i) Import of GM consumption to M/s Solvent Extractors' Association of India in 78th GEAC meeting held on 22.6.07.
- (ii) Import of oil derived from MON89788 from USA to M/s Monsanto Holdings Pvt Ltd, in its 100th meeting held on 12.05.2010

7.1.5 After detailed deliberations the following decisions were taken:

- (i) Sample of GM Soybean oil to be imported by the applicant may be sent to CFTRI, Mysore and CDFD, Hyderabad for compositional analysis for confirmation on whether highly processed food like oil contains detectable level of DNA or proteins as done in the earlier cases.

- (ii) Obtain legal opinion on whether approval for GM foods falls under the mandate of GEAC under Rules 1989 or Food Safety and Standards Authority under the FSSA, 2006.

7.2 Storage of Bt brinjal Seeds at NBPGR

7.2.1 The Committee considered the “Non-Commercial Memorandum of Agreement for Storage of Transgenic Bt Brinjal Seed Material” drafted by ICAR wherein ICAR is the first party, MoEF the second party and M/s Mahyco, UAS Dharwad and TNAU Coimbatore the third party. The Committee also considered the issues raised by M/s Mahyco (applicants) in respect of certain clauses in the agreement and response of ICAR on the matter. The Committee opined that the applicant who is a third party in this case cannot be treated as an equal partner in the regulatory process and therefore certain issues raised by the applicant is not tenable. The Committee requested the legal expert to examine the unresolved issues and give his views on the matter within a weeks’ time subsequent to which M/s Mahyco may be directed to comply with the requirement for storage of Bt brinjal seeds at NBPGR expeditiously.
